Remarks

Rejection Under 35 USC §102(b)

The rejection under 35 USC §102(b) is maintained against Claims 1-5 and 13-18 as allegedly anticipated by Webb et al. Applicants' previous arguments against this rejection have been found persuasive with respect to Claims 2 and 3, on the basis that Webb does not teach or suggest a cycle of therapy consisting of 2 to 13 days. Applicants respectfully submit that the same reasoning applies to Claims 1-5 and 13-18 and supports withdrawal of the rejection with respect to these claims as well.

In maintaining the rejection with respect to Claims 1-5 and 13-18 the Examiner refers to MPEP §2111.03 for an explanation of the transitional phrase "consisting essentially of." This language limits the scope of a claim to the specified materials or steps and additional materials or steps that do not materially affect the basic and novel characteristics of the claimed invention. Claims 1-5 and 13-18, however, do not recite the transitional phrase "consisting essentially of." These claims use the same "consisting of"/"consists of" language used in Claims 2 and 3 where the rejection has been withdrawn. MPEP §2111.03 explains the scope associated with the phrase "consisting of" as follows:

> The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim.....When the phrase "consists of" appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole. *Mannesmann Demag Corp. v. Engineered Metal Products Co.,* 793 F.2d 1279, 230 USPQ 45 (Fed. Cir. 1986).

In Claims 1-5 and 13-18 the phrase "consisting of" appears in the body of the claim and refers to the length of each cycle of therapy, which is 2-13 days. It is therefore unnecessary for Applicants to show that the addition of steps or components to that element of the claim would

materially change the characteristics of the invention, because additional steps or components are excluded by the language used. As the "plus or minus one day of therapy" asserted by the Examiner is excluded, Webb's 14-day cycle of therapy does not anticipate Applicants' cycle of therapy consisting of 2-13 days.

The Examiner's reasons for withdrawing the §102(b) rejection of Claims 2 and 3 applies equally to Claims 1-5 and 13-18. Withdrawal of the rejection is therefore respectfully requested.

Rejection Under 35 USC §103(a) – Claims 1-23

All previous rejections under 35 USC §103(a) have been withdrawn and a new rejection under 35 USC §103(a) has been applied. Claims 1-23 are now rejected as allegedly unpatentable over Webb et al. in view of Bennett et al. (US Patent No. 6,214,986). Webb et al. is relied upon for teaching treating human patients with one cycle of bcl-2 antisense therapy for 14 days and for disclosing daily doses. Again, the difference between Webb et al. and the claimed invention is alleged to be "only plus or minus one day of therapy" (page 6 of the Office Action, lines 1-2 of the last paragraph) and Applicants are requested to show that the introduction of the additional steps or components disclosed by Webb et al. would materially change the characteristics of the invention (page 7 of the Office Action, lines 1-3). As stated above, however, no additional components or steps are encompassed by Applicants' recitation of a cycle of therapy consisting of 2-13 days, and it is unnecessary for Applicants to show that an additional day has a material effect.

Bennett et al. is relied upon for teaching antisense modulation of bcl-x expression and for a broad general discussion of means used in the art for determining dosing schedules, repetition rates, dosages, etc., which are used in the art. Applicants agree that while the methods for

determining doses and treatment schedules are well known, the particular treatment schedule or dose that will be effective for any given drug is not known until it is discovered using these conventional methods. Bennett et al. is therefore no more than an invitation to experiment and, as the antisense drug of Bennett et al. is different from Applicants' bcl-2 antisense drug, any specifics about dosages and treatment schedules for antisense to bcl-x do not suggest anything about appropriate dosages and treatment schedules for the claimed bcl-2 antisense. However, Webb et al. describe a bcl-2 antisense drug similar to that presently claimed, and teach that it should be administered daily in a cycle of 14 days. The references do not create any expectation that an attempt to modify the treatment schedule taught by Webb et al. by experimenting with a wide variety of alternative treatment schedules as suggested by Bennett et al. would result in Applicants' invention, i.e., successful administration of a bcl-2 antisense drug in 2-13 day cycles.

For the foregoing reasons, Applicants submit that the invention of Claims 1-23 would not have been obvious at the time the invention was made, and withdrawal of the rejection is respectfully requested.

Rejection Under 35 USC §103(a) – Claims 29-33

Claims 29-33 are also newly rejected over Webb et al. in view of Bennett et al. Using a similar line of reasoning as in the rejection of Claims 1-23, it is alleged that it would have been obvious to make a pharmaceutical composition for administration in 2-13 day cycles by varying the 14-day cycle of Webb et al. using the general description of Bennett et al. relating to how dosages, treatment schedules and dosage forms are determined. As stated above, Bennett et al. provides no more than a general description of conventional methods for determining treatment schedules for new drugs. It is merely an invitation to experiment and in no way suggests that the

14-day treatment cycle for bcl-2 antisense taught by Webb et al. can be successfully modified to a 2-13 day treatment cycle, as presently claimed.

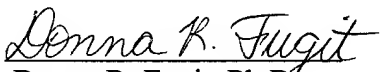
Applicants therefore respectfully request that the rejection of Claims 29-33 as allegedly obvious be withdrawn.

Conclusions

Applicants believe that the claims are in condition for allowance, and an action passing this case to issue is respectfully requested. It is believed that no fees are due in connection with the filing of this paper. However, if fees are due the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-3154.

Respectfully submitted,

Date: October 22, 2004



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